510(k) Summary

K952879

1. **Name and Address of Contact Person**

Scott Beggins
Baxter Healthcare Corporation
CardioVascular Group
Bentley Division
P.O. Box 19522
Irvine, California 92713-9522

APR 22 1996

2. **Name of Device:** 3M™ Sarns™ Centrifugal Pump with Duraflo® II Treatment

3. **Predicate Device:** 3M™ Sarns™ Centrifugal Pump

4. **Device Description**

The Sarns™ Centrifugal Pump is a centrifugal pump which imparts velocity to blood through action of a rotating impeller. The pump is comprised of two chambers. The pump chamber contains the impeller with vanes, seals components, inlet port and outlet port for connection to tubing. The rear chamber contains bearings used to support and align the magnet rotor. The rear chamber is sealed off from the pump chamber. The rear chamber is isolated from atmosphere via a hermetic seal of the housing components forming this chamber. The Duraflo® II Treatment provides a heparin-based blood path containing up to 400 USP units of heparin. This treatment improves the blood compatibility of non-biological surfaces in the extracorporeal circuit.

5. **Intended Use**

The 3M™ Sarns™ Centrifugal Pumps with Duraflo® II Treatment are indicated as extracorporeal pumps for use in cardiopulmonary bypass procedures only and for use exclusively with Sarns™ centrifugal control systems.

6. **a. Technology Comparison**

The proposed device and predicate device are essentially identical with the exception of the addition of the Duraflo® II treatment. Components remain the same.

b. Testing Summary

The following invitro studies were conducted to qualify the 3M™ Sarns™ Centrifugal Pumps with Duraflo®II Treatment:

- Hemolysis
- Platelet Depletion

- White Blood Cells
- Heparin Leaching
- Heparin Quantitation

Test methods were based on the proposed "Special Control Protocol for Evaluation of Blood Trauma Caused by Extracorporeal Centrifugal Pumps". The test results indicated that there was no statistical difference in %PLT depletion or in average % WBC depletion between the coated and uncoated units. While there was a some change noted in hemolysis between the two groups, these results are in line with results from previous centrifugal pump testing at worst case conditions. The test results were also compared to a study that was conducted in early 1995 on the predicate device (K915363).

Functional testing included a 12 hour Life Test (n=16), and a Burst Test (n=16) to test the pump housing, housing welds and mechanical seal under conditions of over pressurization. All Duraflo® II treated pumps passed these tests.

c. Rational for Substantial Equivalence Determination

The coated and uncoated versions of the 3M™ Sarns™ Centrifugal Pumps are essentially identical, basic materials remain the same with the exception being the addition of the Duraflo® II Treatment with the substantially equivalent. Testing has demonstrated that units with the proposed addition of the Duraflo® II Treatment are substantially equivalent to the predicate (uncoated) device, and that there were no adverse effects on overall pump performance.